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10/573,941	01/23/2007	Stewart Francis Ledgard	JAMES68.013APC	5412

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EXAMINER	
HELM, CARALYNNE E	

ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
08/19/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/573,941	LEDGARD, STEWART FRANCIS	
	Examiner	Art Unit	
	CARALYNNE HELM	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 May 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28,30 and 37-67* is/are pending in the application.

4a) Of the above claim(s) *38,39,43-47 and 53-67* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28,30,37,40-42 and 48-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Note to Applicant: References to paragraphs in non-patent literature refer to full paragraphs (e.g. 'page 1 column 1 paragraph 1' refers to the first full paragraph on page 1 in column 1 of the reference)

Election/Restrictions

To summarize the current election, applicants elected Group II and the species where the treatment substance is a nitrification inhibitor, the route of administration is oral and the delivery vehicle is a solution, with traverse.

Claims 38-39, 43-47 and 53-67 were withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The four factual inquiries of Graham v. John Deere Co. have been fully considered and analyzed in the rejections that follow.

Claims 28, 30, 37, 40, 42, 48-49, and 51-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klopfenstein et al. (previously cited) in view of Swerdloff et al. (previously cited), Cookson et al. (previously cited), Davis et al.(previously cited), and Hamilton (previously cited).

Klopfenstein et al. teach that the output of nitrogen in animal waste is lost to the environment via volatilization from manure in contact with soil (e.g. feedlots) (see page 1 column 2 paragraph 1-page 2 column 1 line 6; instant claim 28). Additionally, they teach that it is desirable for manure to be applied to the cropland where the animal feed originated; however, as livestock units have increased in size the plant needs of the local cropland are exceeded by the nitrogen nutrients in the manure produced by the local livestock (see page 2 column 1 paragraph 1). When manure nutrients (e.g. nitrogen) are applied to plants at a rate beyond what they need, the excess nitrogen leaches into the groundwater thereby contaminating the local ecosystem and environment (see page 2 column 1 paragraph 1). It is also taught that much of the nitrogen excreted in cattle urine is volatilized (see page 7 column 1 paragraph 3-column 2 line 2; instant claim 37). Klopfenstein et al. go on to teach that decreasing the nitrogen excreted by livestock can minimize this issue (see page 2 paragraph 2). One

method of reducing nitrogen excreted by livestock taught by Klopfenstein et al. is by the administration of specialized feed additives to the animals (see page 6 lines 10-14; instant claims 49 and 51). While Klopfenstein et al. teach the reduction of nitrogen from soil exposed to waste from an animal by 1) identifying animals whose waste (urine or manure) is applied to soil, 2) orally introducing a treatment substance to the animals and 3) excreting waste from the animals onto the soil, they do not explicitly teach that the additive is a nitrification inhibitor or that the treatment substance is carried in the waste and affects the conversion of nitrogen containing compounds once excreted.

Swerdloff et al. teach a collection of compounds that act as both urease inhibitors and nitrification inhibitors envisioned to reduce the nitrogen lost to the environment from soil (see column 1 lines 29-32 and 50-53 and column 3 line 66-column 4 line 1). Swerdloff et al. also teach the compounds being prepared in liquid (solution) form where water is an envisioned carrier (see column 7 lines 48-50; instant claim 52). They go on to teach that in addition to agricultural applications, the compounds are envisioned for use in other applications where inhibition of urease and/or nitrification is desired (see column 8 lines 54-59). Swerdloff et al. specifically name use as a feed additive as one such application (see column 8 line 61; instant claim 40). Testing of four of the compounds demonstrated that one pair was efficacious as a urease inhibitor and of this pair that one was tested and found to also act as a nitrification inhibitor (see tables I, II, and III).

Cookson et al. teach that dicyandiamide is a nitrification inhibitor known to reduce the loss of nitrate (nitrogen) from cattle urine on soil (see page 1461 column 1 paragraph 1 and page 1464 column 1 paragraph 1; instant claim 42).

Davis et al teach that dicyandiamide was known as an additive in animal feed (see page 515 paragraph 1). Thus one of ordinary skill in the art would have expected this compound to be suitable for oral administration to livestock.

Hamilton teaches that the rumen is the beginning of the digestive tract in ruminant animals (e.g. cattle) serving as a processing site for orally injected substances once that have passed from the mouth and through the esophagus (see page 1 paragraph 2 and figures 1 and 2).

In light of the teachings of Swerdloff et al. that nitrification inhibitors can reduce nitrogen loss from soil and the administration of these inhibitors to animals as feed additives, it would have been obvious to one of ordinary skill in the art at the time of the invention to select a nitrification inhibitor as the feed additive in the method taught by Klopfenstein et al. It would also have been obvious to one of ordinary skill in the art at the time of the invention to safely use dicyandiamide as the feed additive since it was a nitrification inhibitor functionally equivalent to those taught by Klopfenstein et al. in view of Swerdloff et al. and known to be administered orally to animals. Based upon the teachings of Hamilton, oral administration of DCD as taught by Klopfenstein et al. in view of Swerdloff et al., Cookson et al., and Davis et al. would enter the rumen. Applicants' disclosure indicates that upon rumenal administration of DCD, the compound is excreted in the animal's waste and effective at inhibiting nitrification in

urine (see instant specification page 24 lines 23-24). Since the method of Klopfenstein et al. in view of Swerdloff et al., Cookson et al., and Davis et al. also delivers DCD to the animal rumen, it must also be processed in the same fashion. Therefore the method of Klopfenstein et al. in view of Swerdloff et al., Cookson et al., and Davis et al. includes the waste acting as a carrier of the treatment substance (DCD) that affects the conversion of nitrogen containing compounds once the waste is excreted from the animal. Thus claims 28, 30, 37, 40, 42, 48-49, and 51-52 are obvious over Klopfenstein et al. in view of Swerdloff et al., Cookson et al., Davis et al., and Hamilton.

Claims 28, 49, and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klopfenstein et al. in view of Swerdloff et al., Cookson et al., Davis et al., and Hamilton as applied to claims 28, 30, 37, 40, 42, 48-49, and 51-52above, and further in view of Schaefer et al. (previously cited).

Klopfenstein et al. in view of Swerdloff et al., Cookson et al., Davis et al., and Hamilton make obvious the method of instant claims 28 and 40. This modified reference does not explicitly teach administration of the nitrification inhibitor feed additive via drench.

Schaefer et al. teach the administration of a supplement (additive) to an animal by adding it to the food (feed supplement) or via drench, both of which are oral administration routes.

As a known alternative (functionally equivalent means of oral delivery) to feed supplementation, it would have been obvious to one of ordinary skill in the art at the

time of the invention to administer the nitrification inhibitor of Klopfenstein et al. in view of Swerdloff et al., Cookson et al., Davis et al., and Hamilton via a drench. Therefore claims 28, 49, and 50 are obvious over Klopfenstein et al. in view of Swerdloff et al., Cookson et al., Davis et al., Hamilton, and Schaefer et al.

Claims 28, 30, 37, 40-41, 48-49, and 51-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klopfenstein et al. in view of Swerdloff et al., Zerulla et al. (previously cited), and Hamilton.

Klopfenstein et al. teach that the output of nitrogen in animal waste is lost to the environment via volatilization from manure in contact with soil (e.g. feedlots) (see page 1 column 2 paragraph 1-page 2 column 1 line 6; instant claim 28). Additionally, they teach that it is desirable for manure to be applied to the cropland where the animal feed originated; however, as livestock units have increased in size the plant needs of the local cropland are exceeded by the nitrogen nutrients in the manure produced by the local livestock (see page 2 column 1 paragraph 1). When manure nutrients (e.g. nitrogen) are applied to plants at a rate beyond what they need, the excess nitrogen leaches into the groundwater thereby contaminating the local ecosystem and environment (see page 2 column 1 paragraph 1). It is also taught that much of the nitrogen excreted in cattle urine is volatilized (see page 7 column 1 paragraph 3-column 2 line 2; instant claim 37). Klopfenstein et al. go on to teach that decreasing the nitrogen excreted by livestock can minimize this issue (see page 2 paragraph 2). One method of reducing nitrogen excreted by livestock taught by Klopfenstein et al. is by the

administration of specialized feed additives to the animals (see page 6 lines 10-14; instant claims 49 and 51). While Klopfenstein et al. teach the reduction of nitrogen from soil exposed to waste from an animal by 1) identifying animals whose waste (urine or manure) is applied to soil, 2) orally introducing a treatment substance to the animals and 3) excreting waste from the animals onto the soil, they do not explicitly teach that the additive is a nitrification inhibitor or that the treatment substance is carried in the waste and affects the conversion of nitrogen containing compounds once excreted.

Swerdloff et al. teach a collection of compounds that act as both urease inhibitors and nitrification inhibitors envisioned to reduce the nitrogen lost to the environment from soil (see column 1 lines 29-32 and 50-53 and column 3 line 66-column 4 line 1). Swerdloff et al. also teach the compounds being prepared in liquid (solution) form where water is an envisioned carrier (see column 7 lines 48-50; instant claim 52). They go on to teach that in addition to agricultural applications, the compounds are envisioned for use in other applications where inhibition of urease and/or nitrification is desired (see column 8 lines 54-59). Swerdloff et al. specifically name use as a feed additive as one such application (see column 8 line 61; instant claim 40). Testing of four of the compounds demonstrated that one pair was efficacious as a urease inhibitor and of this pair that one was tested and found to also act as a nitrification inhibitor (see tables I, II, and III).

Zerulla et al. teach that 3,4-dimethylpyrazole phosphate is non-toxic nitrification inhibitor known to reduce the loss of minimize the loss of nitrate (nitrogen) from soil (see

page 79 and page 80 column 2 paragraph 6-page 81 column 1 paragraph 1; instant claim 41).

Hamilton teaches that the rumen is the beginning of the digestive tract in ruminant animals (e.g. cattle) serving as a processing site for orally injected substances once that have passed from the mouth and through the esophagus (see page 1 paragraph 2 and figures 1 and 2).

In light of the teachings of Swerdloff et al. that nitrification inhibitors can reduce nitrogen loss from soil and the administration of these inhibitors to animals as feed additives, it would have been obvious to one of ordinary skill in the art at the time of the invention to select a nitrification inhibitor as the feed additive in the method taught by Klopfenstein et al. It would also have been obvious to one of ordinary skill in the art at the time of the invention to safely use 3,4-dimethylpyrazole phosphate as the feed additive since it was a non-toxic nitrification inhibitor functionally equivalent to those taught by Klopfenstein et al. in view of Swerdloff et al. Based upon the teachings of Hamilton, oral administration of 3,4-dimethylpyrazole phosphate as taught by Klopfenstein et al. in view of Swerdloff et al and Zerulla et al. would enter the rumen. Applicants' disclosure indicates that upon rumenal administration of a nitrification inhibitor, the compound is excreted in the animal's waste and effective at inhibiting nitrification in urine (see instant specification page 24 lines 23-24). Since the method of Klopfenstein et al. in view of Swerdloff et al. and Zerulla et al. also delivers an instantly envisioned nitrification inhibitor to the animal rumen, it must also be processed in the same fashion. Therefore the method of Klopfenstein et al. in view of Swerdloff et al. and

Zerulla et al. includes the waste acting as a carrier of the treatment substance (3,4-dimethylpyrazole phosphate) that affects the conversion of nitrogen containing compounds once the waste is excreted from the animal. Thus claims 28, 30, 37, 40-41, 48-49, and 51-52 are obvious over Klopfenstein et al. in view of Swerdloff et al., Zerulla et al., and Hamilton.

Response to Arguments

Applicants' arguments, filed May 28, 2010, have been fully considered but they are not deemed to be persuasive.

In light of the amendment to claim 28, the rejections under 35 USC 103(a) over Klopfenstein et al. in view of Swerdloff et al., over Klopfenstein et al. in view of Swerdloff et al., Cookson et al., and Davis et al., over Klopfenstein et al. in view of Swerdloff et al. and Zerulla, as well as over Klopfenstein et al. in view of Swerdloff et al. and Schaefer et al. are hereby withdrawn. New rejections are presented that address the limitations of claims 30, 37, 40-41, 49, and 50-52 in their newly modified form.

Applicants argue that Klopfenstein et al. teach away from the instant invention because their focus is on reducing the amount of nitrogen excreted by the animal. As discussed in the rejection, the goal of Klopfenstein et al. is to reduce the amount of nitrogen lost to the environment from the waste of livestock that is released onto soil, contaminating the air and ground water. The instant invention also seeks to reduce the

loss of nitrogen from soil due to the presence of animal waste. The same detrimental outcomes to the environment are highlighted by both Klopfenstein et al. and the instant inventors (see instant specification page 1 line 19-page 2 line 10). Thus the teachings of Klopfenstein et al. are not directed away from those of the instant invention. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., retention of nitrogen in the soil) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In response to applicants' argument that the combination of prior art cited did not suggest administration of treatment compounds to animals to affect the conversion of nitrogen based compounds after waste products are excreted from the animals where the waste acts as a carrier for the treatment compounds, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). The prior art references would have motivated one of ordinary skill in the art to 1) identify a cow whose waste (urine or manure) is applied to soil, 2) orally introduce a nitrification inhibitor to the cow and 3) excrete waste from the cow onto the soil, resulting in the reduction of nitrogen lost from the soil exposed to the waste as compared to waste from a cow where the nitrification inhibitor was not introduced. There would have been a reasonable expectation of success for this method because Swerdloff et al.

explicitly teach the use of their envisioned nitrification inhibitors as feed additives in applications where the inhibition of nitrification is desired. Further, they contemplate animal waste that is ultimately deposited onto soil as an instance where the inhibition of nitrification would be desirable. Applicants even suggest that the administration of these compounds as a feed supplement would result in improving the utilization of dietary nitrogen, which would still meet the goal of reduced nitrogen loss put forth by Klopfenstein et al. The teachings of Cookson et al., Davis et al., and Hamilton et al. motivate the oral (which ultimately empties into the rumen) administration of the same compound taught by applicants to effect nitrogen conversion in waste after it is administered to the rumen and waste is excreted, thus the method made obvious by their combination must also act via the same pathway claimed by applicants (e.g., waste acts a carrier for nitrification inhibitor and acts on nitrogen containing compounds once waste is excreted). The discovery of the mechanism by which an obvious method occurs does not change the method or define a new, patentably distinct method.

The rejections and/or objections detailed above are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Friday 9-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on 571-272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Caralynne Helm/
Examiner, Art Unit 1615

/Robert A. Wax/
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